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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/764,710 | 01/17/2001 | Michael Konkel | 54927-A-PCT-US/JPW/ADM | 7575 |

7590 08/27/2002

John P. White
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EXAMINER

SMALL, ANDREA D SOUZA

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1626

DATE MAILED: 08/27/2002

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/764,710

Applicant(s)

KONKEL ET AL.

Examiner

Andrea D Small

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) parts of 1-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 13-15, 22, 26-30 and 32 is/are rejected.
- 7) ☒ Claim(s) 7-12, 16-21, 23-25, 31 and 33-37 is/are objected to.
- 8) ☒ Claim(s) 38-42 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5,6. 6) ☐ Other: _____

DETAILED ACTION

I. Applicant's Response:

Applicant's response dated 8/1/02 has been received and entered as paper no. 10.

II. Election/Restriction:

Applicant's have elected to prosecute group I, drawn to compounds according to claim 5 wherein X is N.

III. Applicant's Traversal:

Applicants traverse the restriction requirement by stating that group I and group II are not independent, and therefore, the claims are not restrictable.

The examiner respectfully disagrees. The restriction between the two groups is based on the fact that the two groups are indeed distinct and independent. Inventions of group I and group II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, the compounds of group I have not been shown to be used with the compounds of group II, additionally, the two compounds would have different modes of operation in that their molecular size and geometry are different and thus would have effects which are not the same or to the same extent.

For these reasons and the reasons provided in the previous office action, the restriction as outlined is proper and made FINAL.

The remainder of claims 1-42 are withdrawn as being drawn to non-elected subject matter. 37 CFR 1.142(b).

IV. Rejections:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 22, 26-30 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Wu, et al, cited.

Applicants claim phenyl substituted azaspiro piperizine compounds according to the formula in claim 1, their pharmaceutical compositions and their corresponding methods of use as adrenergic receptor antagonists.

The Wu, et al reference also teaches phenyl substituted azaspiro piperizine compounds that fall within the genus of the compounds as instantly claimed, specifically where, Y and Z is C(=O); R1 and R2 form a ring; X is N; R3-R8 is H; R9-R13 are H, CH3, OMe, Cl, etc. See table I A and IB on page 877. Wu also teaches that these compounds are useful to antagonize amphetamine aggregation, which is inherently related to the adrenergic system. Therefore, providing the same host, mammal, with the same drug, see above, would inherently treat and inhibit the same disease and receptor as is instantly claimed. Therefore, the above-cited claims are anticipated.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 6 and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wu, et al.

Applicants claim phenyl substituted azaspiro piperizine compounds according to the formula in claim 1, their pharmaceutical compositions and their corresponding methods of use.

Determination of the scope and content of the prior art (MPEP §2141.01)

The Wu, et al reference also teaches phenyl substituted azaspiro piperizine compounds that fall within the genus of the compounds as instantly claimed, specifically where, Y and Z is C(=O); R1 and R2 form a ring; X is N; R3-R8 is H; R9-R13 are H, CH3, OMe, Cl, etc. See table I A and IB on page 877. Wu also teaches that these compounds are useful to antagonize amphetamine aggregation, which is inherently related to the adrenergic system.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the prior art and the instant claims is that the instant claims have a fluorine instead of a chlorine at the R9 position.

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Finding of prima facie obviousness---rational and motivation (MPEP §2142-2413)

However, it would have been prima facie obvious for one of ordinary skill in the art at the time of the filing of the instant application to substitute a fluorine for a chlorine on the compounds because in to one of ordinary skill in the art, fluorine and chlorine are considered analogues or isologues of each other and thus would be expected to have the same or similar activity. *Ex parte Wiseman*, 98 USPQ 277 (1953), it was held that compounds are rejected over prior art when the difference between the claimed compounds and the compounds of the prior art is two fluorine atoms versus chlorine atoms. The basis of this reasoning is that fluorine and chlorine are both halogen elements from the seventh group of the periodic system and the claimed compound is thus an analogue or an isologue of that disclosed in the prior art. The compounds are expected to possess similar properties differing only in degree.

V. Objections:

Claims 7-12, 16-21, 23-25, 31 and 33-37 are objected to as being dependent on rejected base claims and would appear allowable if rewritten in independent form.

VI. Allowed Claims:

Claims 38-42 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrea D. Small, whose telephone number is (703) 305-0811. The examiner can normally be reached on Monday-Thursday from 8:30 AM - 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (703) 308-4537. The Unofficial fax phone number for this Group is (703) 308-7921. The Official fax phone numbers for this Group are (703) 308-4556 or 305-3592.

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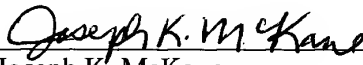
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documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [Joseph.McKane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-1234

Andrea D. Small
August 26, 2002



Joseph K. McKane
Supervisory Patent Examiner
Art Unit 1626
Technology Center 1